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Guidance for the Reregistration of Pesticide Products Containing Aluminum Tris(O-Ethylphosphonate) as the Active Ingredient

(U.S.) Environmental Protection Agency, Washington, DC

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

ALUMINUM TRIS(O-ETHYLPHOSPHONATE)
(REFERRED TO AS FOSETYL-AL)

AS THE ACTIVE INGREDIENT

CASE NUMBER: 0646

CAS (DOCKET) NUMBER 39148-24-8

FEBRUARY, 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI: (Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a complete data base.

ai: Active Ingredient

CAS: Chemical Abstract Service (Number)

Core Classifications: A general guide to the acceptability of data for the purpose of supporting registration (invalid, supplementary, minimum, or guideline).

Core Guideline: Studies which satisfy Agency data requirements.

Core Minimum: Studies which are acceptable to support registration of pesticide products but were not necessarily done according to Agency guidelines.

Core Supplementary: Studies in this category are scientifically sound, thus the information may be useful. However, the studies were performed under conditions that deviated substantially from recommended protocols. Studies do not meet guideline requirements and thus do not support registration of a product.

CSF: Confidential Statement of Formula

DNA: deoxyribonucleic acid

EEC: (Estimated Environmental Concentration) Estimated pesticide concentration in the environment (terrestrial or aquatic ecosystem).

EP: End-Use Product

EPA: The Environmental Protection Agency, also "the Agency"

Epicotyl - The growing point of the embryo, which gives rise to the shoot, or aboveground part of the plant.

F_0, F_1: Refers to the generations in a multigeneration study.

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act

HDT: Highest Dose Tested

Invalid: Studies which are deficient in some vital parameter or those studies which have been judged not to be scientifically sound or those studies whose reliability is seriously questioned.

Interim Tolerance - As per 40 CFR 180.319, interim tolerances were formerly established for residues of various pesticides while petitions for tolerances for negligible residues were pending. Note that negligible residue tolerances are no longer established.

LC_{50}: (median lethal concentration) a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volume of test substance per volume of air or water (e.g., mg/L or ppm).

LD_{50}: (median lethal dose) a statistically derived single dose that can be expected to cause death in 50% of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

LDT: Lowest Dose Tested

LEL: Lowest-Effect Level

MDT: Mid-Dose Tested

MOS: Margin of Safety - The calculation of a margin of safety involves division of an appropriate NOEL by a worker's estimated exposure. The result is a unitless figure which gives an indication of how close a worker's internal dose is in relation to the NOEL for laboratory animals.

MP: Manufacturing-Use Product

MPI: Maximum Permissible Intake

MRID: Master Record Identification (Number) - EPA's system of tracking studies used in support of registrations.

NPDES: National Pollution Discharge Elimination System

NOEL: No-Observed-Effect Level --the maximum dose used in a test which produces no observed effects.

OPP: The Office of Pesticide Programs

OES: Office of Endangered Species, U.S. Fish and Wildlife Service

OM: Organic matter (used to describe soils)

PADI: Provisional Acceptable Daily Intake --an acceptable daily intake of pesticide residue based on a limited data base.

PAI: Pure Active Ingredient

ppm: parts per million

RACs: Raw Agricultural Commodities

Technical: Active ingredient as manufactured

TGAI: Technical Grade of the Active Ingredient

TMRC: Theoretical Maximum Residue Contribution --an estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure, then adding the exposure figures for each crop. TMRC is usually expressed in terms of milligrams of active ingredient per kilogram body weight per day.

I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard, issued in June 1983, the Agency described the available data supporting the registration of the chemical and its assessment of those data in terms of whether the pesticide met the "no unreasonable adverse effects" standard of FIFRA. The Agency concluded that additional data were necessary to fully evaluate the pesticide, and, as part of the issuance of the Standard, required that registrants supply those data. The Agency also set out label requirements needed to ensure that products containing the pesticide were adequate to protect public health and the environment while the data were under development.

The Agency has now received and reviewed the new data and has updated and revised its scientific and regulatory conclusions concerning the pesticide. The Registration Standard contains the Agency's updated scientific assessment of this pesticide and its currently registered uses. As part of its review, the Agency has reassessed the tolerances for the pesticide and determined whether they are adequate. The tolerance reassessment is included in this Registration Standard.

In the intervening period between the original standard and this revision, the Agency has expanded its data requirements. Consequently this Registration Standard may contain additional data requirements not foreseen or required at the time of initial issuance. Based on the new data, the Agency has also reviewed the labeling requirements for the pesticide and may be requiring label revisions.

In this review EPA identifies:

1. Studies that are acceptable to fulfill the data requirements and support the currently registered uses of the pesticide.

2. Additional studies necessary to support registration or reregistration. The additional studies may not have been required when the application was initially submitted or when the product was initially registered, or may be needed to replace studies that are now considered inadequate.

3. Labeling statements needed to ensure that the product

is not misbranded and that the labeling is adequate to protect human health and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect human health and the environment.

EPA's reassessment results in the development of regulatory positions, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory positions, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases of registered pesticides for which hazards to humans or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve its concerns about this pesticide. These data are listed in Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements may result in the issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as a product is registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of chemical

The following chemical is covered by this Registration Standard:

Common name: None[1]
Chemical name: Aluminum tris(O-ethylphosphonate) (Referred to hereafter as fosetyl-Al)
CAS Number: 39148-24-8
OPP Shaughnessy Number: 123301
Empirical Formula: $Al(H_6C_2O_3P)_3$
Trade name: Aliette
Description of physical characteristics of chemical:

Fosetyl-Al is a white odorless powder that melts with decomposition at temperatures greater than 200° Celsius. The solubility of fosetyl-Al in water at 20° Celsius is 120 grams per liter. The chemical is stable under normal storage conditions.

B. Use Profile

Type of Pesticide: Systemic fungicide
Pests Controlled: Oomyceteous fungi causing damping-off and rot of roots, stems and fruit.
Registered Uses: Pineapples; Citrus; Ornamentals; Turf
Predominant Uses: Pineapples; Citrus; Ornamentals
Mode of Activity: Unknown
Formulation Types Registered:
Technical - 95 percent active ingredient
Formulation - 80 percent wettable powder

Methods of Application: Dip treatment; Pre-plant soil Incorporation; Foliar; Drench

C. History

Fosetyl-Al was first registered by the Agency in 1983 for use on pineapples, ornamentals and turf. The chemical is sold under the trade name Aliette®. It is known in England as fosetyl-Al and in France as phosetyl-Al. It has a discontinued common name of efosite-Al. The uses of fosetyl-Al for foliar application to pineapple and to citrus were added in 1985 and 1986, respectively.

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[1] For the purpose of the standard, the name, fosetyl-Al, is used rather than Aluminum tris(O-ethylphosphonate).

III. AGENCY ASSESSMENT

A. Summary

The Agency has reviewed all data submitted to support the registration of fosetyl-Al. Based on the review and evaluation of these data, the Agency has reached the following conclusions. A detailed discussion of the points summarized below appears in Section B of this Chapter.

1. Fosetyl-Al poses a limited oncogenic risk to the general population as a result of exposure through the diet and to persons who may be exposed during the application of the chemical. This is based on limited evidence of carcinogenicity in animal data. The animal data indicates a statistically significant increased incidence of urinary bladder tumors (adenomas and carcinomas combined) in male rats administered fosetyl-Al at the highest dose tested (40,000/30,000 ppm). There are no human data on the effects of fosetyl-Al. Based on these data, fosetyl-Al is classified as a Group C (possible human) carcinogen.

2. As stated in the Guidelines for Carcinogen Risk Assessment (51 FR 33992) it may be necessary for the Agency to determine, on a case-by-case basis, whether a Group C carcinogen is suitable for quantitative risk assessment. In the case of fosetyl-Al, the Agency has determined that a quantitative oncogenic risk assessment is not appropriate. The available data do not provide a suitable basis for numerical extrapolation to humans for the following reasons:

   a. The incidence of urinary bladder tumors was not a strictly dose-related phenomenon. The response was observed only in male rats at the highest dose tested (40,000/30,000 ppm).

   b. The extremely high doses tested (40,000/30,000 ppm) approached the level of 5% of the diet which could begin to compromise the nutritional status of the experimental animals, due to the dilution of essential nutrients. Moreover, the Agency is now tentatively proposing that the maximum tolerated dose for rats should not exceed 20,000 ppm in oncogenicity studies.

   c. Stress produced by administering extremely high doses of chemicals to laboratory animals can enhance the response to oncogenic viruses and perhaps other innate carcinogens as well (Paynter, Standard Evaluation Procedure for Evaluation of Oncogenicity Potential, June 1985, page 24). High doses of fosetyl-Al (40,000/30,000 ppm) may have produced stress, allowing a second substance to produce the carcinogenic response or facilitating a neoplastic process.

   d. All mutagenicity tests on fosetyl-Al were negative.

3. The review of fosetyl-Al is the second intensive evaluation of the compound. A registration standard was developed in 1983 in conjunction with its initial registration. There are no major data gaps. A draft revised Registration Standard for fosetyl-Al was issued for public comment in December 1986. No comments were received on the draft Standard. Since the issuance of the standard in 1983, the Agency has published the data requirements for registration. Based on these requirements, the Agency will require the following data:

§158.125 Residue Chemistry

171-4 Storage Stability of Residues in Pineapples and Citrus

Storage stability data for pineapples and citrus are required reflecting sample storage time between harvest and analysis. Recent information reviewed by the Agency has indicated that fosetyl-Al is less stable than previously characterized.

§158.140 Reentry Protection

132-1 Foliar Dissipation

Data are required to establish a reentry interval for farmworkers and maintenance personnel on all crops that require hand harvesting, pruning, and other high intensity worker contact with treated foliage due to potential eye irritation.

§158.150 Plant Protection

122-2 Aquatic Plant Growth

This study is required due to the persistence of fosetyl-Al in water.

§158.155 Nontarget Insects

141-1 Honeybee Acute Contact LD_{50}

This study is required because use on crops may result in exposure of honeybees.

B. Risk Assessment.

The Agency has conducted a thorough review of the scientific data base for fosetyl-Al. The conclusions and requirements imposed as a result of this review and evaluation are summarized in Section III-A. A discussion of the results of the review of the data base is presented below.

1. Acute and Subacute Toxicity. Adequate data are available to determine the acute toxicity of fosetyl-Al. Based on the available data, technical fosetyl-Al (purity 98.4%) is classified as a Toxicity Category I chemical based on eye irritation. For the other exposure routes fosetyl-Al is classified as a Toxicity Category III or IV chemical.

Available data define the approximate LD_{50} values for oral and dermal exposure and the LC_{50} for inhalation exposure. The LD_{50} for acute oral (rat) and dermal (rabbit) exposure are 5.4 g/kg and >2g/kg, respectively, and the LC_{50} for inhalation (rat) is >1.73 mg/l. A primary eye irritation study indicated the chemical was irritating to the eye of the rabbit, with cornea involvement persisting at 21 days in 2 of the 6 treated animals (eyes not rinsed).

Data show that fosetyl-Al is not a skin sensitizer. No additional dermal sensitization data are needed.

Acute toxicity data are available on Aliette® (80% WP). Acute oral (rat) and dermal (rabbit) toxicity LD_{50} values are >5 g/kg and >2 g/kg, respectively. The acute inhalation toxicity LC_{50} (rat) value is >2.67 g/l. Based on eye irritation data, Aliette® is classified as a Toxicity Category III product. No additional acute toxicity data are required.

2. Chronic Feeding/Oncogenicity Studies.

Rat Oncogenicity Study - Fosetyl-Al was administered in the diet to 80 Charles River CD-1 rats/sex/dose level at doses of 0, 2000, 8000 and 40,000/30,000 (0, 100, 400, and 2000/1500 mg/kg body weight/day) for two years. The high level was reduced to 30,000 ppm after 2 weeks, following observations of staining of the abdominal fur and red coloration of the urine at 40,000 ppm. No clinical signs were noted at the 2000 and 8000 ppm levels and no NOEL for systemic effects was established.

The study demonstrated a statistically significant elevated incidence of urinary bladder tumors (adenomas and carcinomas combined) at the highest dose level tested (40,000/30,000 ppm) in male Charles River CD-1 rats. The tumors were mainly seen in surviving males at the time of terminal sacrifice. The original pathological diagnosis of these tumors was independently confirmed by a second consulting pathologist, who also reported an elevated incidence of urinary bladder hyperplasia in male rats at the high dose level (Table 1). No elevated incidence of urinary bladder tumors was observed in female rats.

The original diagnosis of adrenal medullary tumors (pheochromocytomas) indicated there was a statistically significant increase in pheochromocytomas (adenomas plus carcinomas combined) in male rats at the mid (8000 ppm) and high (40,000/30,000) dose levels (Table 1; pathologist No.1). The elevated pheochromocytoma incidence was primarily due to an increase in the adenomas; no elevated incidence of adrenal medullary hyperplasia was observed. Furthermore, when all 3 adrenal medullary lesions were combined (i.e., adenomas, carcinomas and hyperplasia), no significant dose-related effects were reported by pathologist No. 1.

This diagnosis was not confirmed by two other consulting pathologists who reread the male rat adrenal gland slides (Table 1; pathologists No. 2 and No. 3). Neither consulting pathologist found significant dose-related increases in the incidence of pheochromocytomas (adenomas plus carcinomas combined) in male rats treated with fosetyl-Al. None of the three pathologists reported increased incidences of combined of adrenal medullary lesions (i.e., adenomas, carcinomas, and hyperplasia). The Agency attributed the differences in the pathological diagnosis of pheochromocytommas among the three pathologists to the fact that a high degree of variability exists in the interpretation of adrenal medullary neoplasia versus adrenal medullary hyperplasia.

Pathologist No. 3, a known authority in the field of endocrine pathology, was requested by the Agency to read all of the slides blindly. Based on this reading of the slides and wide variability in the interpretation of adrenal medullary neoplasia versus hyperplasia, the Agency concluded that fosetyl-Al did not produce an increased incidence of pheochromocytomas in the high dose male rats. No elevated incidence of adrenal gland tumors was observed in female rats.

Rat Oncogenicity Study with Monosodium Phosphite (a metabolite of Fosetyl-Al) - Monosodium phosphite, the urinary metabolite of fosetyl-Al in the rat, was administered in the diet to 60 Charles River CD-1 rats/sex/dose level at doses of 0, 2,000, 8,000, and 32,000 ppm (0, 100, 400, and 1600 mg/kg body weight/day) for 117 weeks. The dose levels tested in this study were equivalent to those employed in the chronic oncogenicity study of fosetyl-Al described above. No evidence of an oncogenic response in the urinary bladder, the adrenal medulla, or at any other site was observed in this study.

TABLE 1

Pathology Diagnoses of Urinary Bladder and Adrenal Medullary Tumors in Oncogenicity Feeding Study of fosetyl-Al in Male Charles River CD Rats

Tumor Site and Type	Reviewing[a/] Pathologist	Dose (ppm) 0	2,000	8,000	40,000/ 30,000
Urinary Bladder:					
Adenoma	1	0/80(0%)	1/78(1%)	1/79(1%)	8/80(10%)
	3	1/80(1%)	1/78(1%)	1/79(1%)	5/80(6%)
Carcinoma	1	2/80(2.5%)	0/78(0%)	0/79(0%)	7/80(9%)
	3	2/80(2.5%)	2/78(2.5%)	1/79(1%)	16/80(20%)
Adenoma + Carcinoma Combined	1	2/80(2.5%)	1/78(1%)	1/79(1%)	15/80(19%)*
	3	3/80(4%)	3/78(4%)	2/79(2.5%)	21/80(26%)
Hyperplasia	1	NA	NA	NA	NA
	3	5/78(6%)	7/78(9%)	5/80(6%)	29/79(37%)
Adrenal Medulla:					
Adenoma	1	5/80(6%)	7/78(9%)	15/79(19%)	16/80(20%)
Carcinoma	1	1/80(1%)	0/78(0%)	1/79(1%)	2/80(2.5%)
Adenoma + Carcinoma Combined	1	6/80(7%)	7/78(9%)	16/79(20%)*	18/80(22%)*
	2	17/80(21%)	15/78(19%)	19/79(24%)	21/80(26%)
	3	6/80(7%)	5/78(6%)	10/79(13%)	6/80(7%)
Hyperplasia	1	16/80(20%)	11/78(14%)	10/79(13%)	9/80(11%)
	2	5/80(6%)	3/78(4%)	5/79(6%)	4/80(5%)
	3	15/80(19%)	14/78(18%)	13/79(13%)	16/80(20%)
Adenoma + Carcinoma + Hyperplasia (Combined)	1	22/80(27%)	18/78(23%)	26/79(33%)	27/80(34%)
	2	22/80(27%)	18/78(23%)	24/79(30%)	25/80(31%)
	3	21/80(26%)	19/78(24%)	23/79(29%)	22/80(27%)

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a/ 1 = Dr. R. M. Kovatch (Original Pathology Report)
2 = Dr. W. R. Richter (Consultant; Examined Limited Slides)
3 = Dr. S. W. Thompson (Consultant; Examined All Slides Blindly)

* $p < 0.05$ compared to controls (Note: Statistical evaluation of data was presentec only for the diagnosis provided by pathologist No. 1).

NA = Information Not Available

The highest dose of monosodium phosphite tested in the study was associated with the following signs of toxicity: (a). a significant ($p< 0.05$) reduction in mean body weight gain in male rats (-13.8%) and female rats (-9.4%) (throughout the study this effect appeared to be compound related for the males since weight gain was also reduced in low dose males (-9.5%) and in mid dose males (-15.4%) at the end of the study); (b). a reduction in the efficiency of food utilization in male rats (this effect, which also occurred in the mid dose males, may have been related to the reduced rate of weight gain seen in male rats); (c). soft stools in male rats; (d). a slight reduction in urine pH (acidification) in male rats, and (e). significant ($p<0.05$) increases in relative weights of the liver (male rats), kidneys (male and female rats), and the heart (male and female rats). It was concluded that, although most of these changes would not satisfy the usual criteria for meeting a maximum tolerated dose (MTD) level, the high dose level of 32,000 ppm (3% of the diet) was approaching a level that affected nutrition.

Mouse Oncogenicity - Fosetyl-Al was administered in the diet to 60 Charles River CD-1 mice/sex/dose level at doses of 0, 2,500, 10,000, and 20,000/30,000 ppm (0, 357, 1,430, 2,857/ 4,286 mg/kg body weight/day) for 2 years. The high dose level was increased from 20,000 ppm to 30,000 ppm at study week 19 because of the absence of any observable effect in the early part of the study. No evidence of an oncogenic response was observed with fosetyl-Al, and no other toxicological changes were seen.

The highest dose of fosetyl-Al tested in this study (i.e., 20,000/30,000 ppm) did not approximate a MTD level. The registrant apparently set the dose levels in this study on the basis of those used in the chronic rat oncogenicity study, since no subchronic toxicity tests were performed in mice to estimate the MTD level. The initial dose levels used in the mouse study were extremely high and were increased at week 19 of the study. The animals received a high enough dose throughout the study to demonstrate any toxic effects. The Agency does not believe that additional oncogenicity testing in mice would increase an understanding of the chemical's toxicity since the high dose level of 20,000/30,000 ppm (2% of the diet) was approaching a level that affected nutrition.

Two Year Dog Feeding Study - Fosetyl-Al was administered in the diet to 6 dogs/sex/dose level at doses of 0, 10,000. 20,000, and 40,000 ppm (0, 250, 500, and 1,000 mg/kg body weight). The no-observed-effect-level (NOEL) was 10,000 ppm. The lowest effect level (LEL) was 20,000 ppm based on testicular changes (i.e. presence of spermatocytic and/or spermatidic giant cells in the lumen of the seminiferous tubules) in 2/6 males; this effect was also observed for 6/6 high dose male dogs. Other changes that were seen only at the high dose level consisted of a reduction in total serum proteins in male dogs throughout the study and a reduced BUN in female dogs at several study intervals. No other toxicological or histopathological effects were observed.

The Agency has concluded that the data available constitutes limited evidence of oncogenicity under the EPA Guidelines for Carcinogen Risk Assessment (September 24, 1986, 51 FR 33992). Therefore, fosetyl-Al is classified as a Group C carcinogen (limited evidence of carcinogenicity in animals). The Agency has determined that a quantitative oncogenic risk assessment is not appropriate. The classification and the decision on not to perform a quantitative risk assessment are based on the following:

a. The oncogenic response observed with fosetyl-Al were confined solely to the high dose males at one site (urinary bladder) in Charles River CD-1 rats. The tumors were mainly seen in surviving animals at the time of terminal sacrifice. Moreover, the unusually high dose at which oncogenic effects were observed (40,000/30,000 ppm) approached a level in the diet at which the nutritional status of the experimental animals may begin to be compromised.

b. Fosetyl-Al was not oncogenic when administered in the diet to Charles River CD-1 mice at dose levels ranging from 2,500 to 30,000 ppm.

c. Stress produced by administering extremely high doses of chemicals to laboratory animals can enhance the response to oncogenic viruses and perhaps other innate carcinogens as well (Paynter, Standard Evaluation Procedure for Evaluation of Oncogenicity Potential, June 1985, page 24). High doses of fosetyl-Al (40,000/30,000 ppm) may have produced stress, allowing a second substance to produce the carcinogenic response or facilitating a neoplastic process.

c. The urinary metabolite of fosetyl-Al, monosodium phosphite, was not oncogenic when administered in the diet to Charles River CD-1 rats at dose levels ranging from 2,000 to 32,000 ppm.

d. No adverse effects on the urinary bladder or the adrenal gland were produced by fosetyl-Al in a 2-year chronic toxicity study performed in Beagle dogs at dose levels ranging from 10,000 to 40,000 ppm.

e. Fosetyl-Al was not mutagenic in eight genotoxicity assays.

3. Reproduction Study - A three generation rat reproduction study was carried out at doses of 0, 6,000, 12,000, and 24,000 ppm (0, 300, 600, and 1,200 mg/kg body weight). There was no evidence of an adverse effect on fertility or reproduction at any dosage. Similarly there was no indication of an adverse effect on *in utero* or on the development of young. Parental animals were adversely affected at the highest concentration (24,000 ppm) and to a lesser extent at 12,000 ppm but not at 6,000 ppm. At 24,000 ppm the most noteworthy effects were:

(a). Lower body weight gain for males of all generations, and females of the F1B and F2B generation; the more marked deviations of the F1B and F2B generations were associated with both higher ingestions of material and lower weight at weaning. (b). For all generations a specific effect on the pattern of maternal weight changes during lactation leading to slower mean pup weight gain and lower litter and mean pup weights in mid- and late lactation. (c). A high incidence of animals showing pathological changes in the urinary tract, particularly for the F1B and F2B generations. These pathological changes in the urinary tract were associated with an increased incidence of male but not female deaths for the F1B and F2B generations. (d). Correlating with urinary tract changes observed in adults, the more detailed microscopic examination at weaning of 10 male and 10 female per group (F3B generation) revealed crystalline or calcareous deposits in the lumen of the urinary bladder of most animals. The presence of these deposits was frequently associated with minimal hyperplasia/hypertrophy of transitional epithelium and sometimes also with papillary projections and/or desquamation of epithelial cells. These epithelial abnormalities are most likely reactive to the presence of crystalline, calcareous deposits in the bladder.

Similarly, at 12,000 ppm the following less marked effects were observed: lower overall weight gains of the F2B generation, lower litter and mean pup weight in late lactation, and urinary tract changes in some adults and 10% weanling males of the F3B generation. The NOEL in this study is considered to be 6,000 ppm in adult and young rats (300 mg/kg and 600 mg/kg, respectively).

4. Teratogenicity Studies - Fosetyl-Al did not induce any embryotoxic, fetotoxic, or teratogenic effects when orally administered to pregnant New Zealand White rabbits at dose levels of 125, 250 and 500 mg/kg body weight/day. The maximum tolerated dose was 250 mg/kg body weight/day based on significantly lower weight gain in pregnant dams.

Fosetyl-Al was orally administered to rats at levels of 0, 500, 1,000, and 4,000 mg/kg body weight. The treatment with fosetyl-Al caused maternal toxicity at the highest dose tested (4,000 mg/kg body weight/day). As a result of maternal toxicity effect at this dose level, litter and mean fetal weights were reduced, total resorptions were increased and delayed ossification of fetuses were observed. Five of 20 pregnant dams died at the high dose. The NOEL for this study is considered 1,000 mg/kg body weight/day.

5. Mutagenicity Studies - Eight mutagenicity tests were performed with fosetyl-Al. All were acceptable to the Agency and all were negative for mutagenic effects. These included two Ames tests using *S. typhimurium* (strains TA 98, TA 1535, TA 1537, and TA 1538), two phage induction tests using *E. coli*, two micronucleus tests in Swiss mice and CD-1 mice (no increase in the percentage of polychromatic erythrocytes with micronuclei was observed), one DNA repair test using *E. coli*, and one *Saccharomyces cereviscae* yeast assay.

6. Metabolism Studies - Two studies were conducted in Sprague-Dawley (SD) rats with orally administered C^{14} fosetyl-Al (250 mg/kg body weight/day X 7 days). The compound was rapidly metabolized to give mainly CO_2 (60%) which was recovered from exhaled air. The second major route of excretion was via the urine (approximately 26%) which contained some unchanged parent compound plus a larger amount of phosphite (phosphorus acid) as a metabolite, but no phosphate. Only minor amounts (3-4%) of administered radioactivity were found in feces and this consisted mainly of the phosphite metabolite. Two additional studies were conducted in SD rats with the P^{32} labeled phosphite metabolite (111 mg/kg body weight/day X 7 days). The phosphite was excreted unchanged in both the urine (59-65%) and the feces (30-32%). No unusual localization of either fosetyl-Al or the metabolite in tissues was observed. From the above results it appears that fosetyl-Al is essentially completely absorbed after oral ingestion and extensively hydrolyzed to phosphite and acetate to CO_2 and then excreted in expired air. The phosphite is excreted (along with some unchanged parent compound) directly into the urine without further oxidation to phosphate.

7. Other Scientific Findings.

Environmental Fate - The environmental fate of fosetyl-Al is sufficiently understood to conclude that no accumulation of the chemical will result and because of rapid degradation, it will not pose a potential a ground water contamination hazard. Fosetyl-Al degrades in the environment through the hydrolysis of the ethyl ester bond with subsequent degradation of the ethanol into carbon dioxide. The phosphorous acid metabolite is expected to form precipitates with aluminum, calcium, or iron in the soil. The half-life of fosetyl-Al under aerobic conditions in soil is approximately 1.5 hours. The intermediate metabolites in grapes, pineapples and the rat are ethanol and phosphorous acid.

Ecological Effects. Fosetyl-Al is not expected to pose a significant hazard to terrestrial or aquatic organisms. The toxicity of fosetyl-Al ranges from slightly toxic to practically non-toxic. Freshwater fish are in the slightly toxic category; grass shrimp and eastern oyster are in the moderately toxic category, respectively. The remaining species (mammalian, avian, estuarine fish, and freshwater invertebrates) are in the practically nontoxic category. Therefore, the estimated concentrations of fosetyl-Al in the environment are not expected to reach levels toxic to non-target organisms, including endangered species.

D. Tolerance Reassessment.

Tolerances have been established in 40 CFR 180.415 for residues of fosetyl-Al in or on citrus, pineapple, and pineapple forage at 0.1 ppm. There are no Codex tolerances for fosetyl-Al. EPA has evaluated the residue and toxicology data supporting tolerances, and has made the following regulatory determinations:

1. The data submitted have been judged adequate to support the existing tolerances. The established tolerances are set at the appropriate levels and no new tolerances are required to cover the existing uses for the registered product. The established tolerances have an adequate margin of safety to protect the public health.

2. An oncogenicity study in mice was conducted in which no oncogenic effects were induced at any dose level under the conditions of the study (the highest dose tested was 2,857/4,286 mg/kg body weight/day).

3. A rat chronic feeding/oncogenicity study was conducted in which a NOEL for systemic effects was not demonstrated. A statistically significant increase in the incidence of urinary bladder tumors was noted at the highest dose tested (40,000/30,000 ppm). The incidence of these tumors was not a strictly dose-related phenomenon since the response was only at the highest dose tested. These high doses could begin to compromise the nutritional status of the experimental animals and also produce stress which could enhance the response to oncogenic viruses.

4. A dog feeding study demonstrated a NOEL of 250 mg/kg body weight/day.

5. A reproduction study in rats demonstrated a NOEL of 300 mg/kg body weight/day.

6. A teratology study in rabbits showed no teratogenic effects and a NOEL of 500 mg/kg/day based on maternal toxicity.

7. A teratology study in rats demonstrated no teratogenic effects and a NOEL of 1,000 mg/kg/day based on maternal toxicity.

8. Ames mutagenicity assays, E. Coli phage induction tests, micronucleaus tests in mice, DNA repair tests using E. Coli, and Saccharomyces cervisiae yeast assay were all negative for mutagenic effects.

9. There are two analytical methods acceptable for determining the levels of residues of fosetyl-Al in plants. A gas chromatography method for pineapples with an analytical sensitivity of 0.1 ppm and a phosphorous specific flame photometric gas chromatography method for citrus with an analytical sensitivity of 0.02 ppm. Harvested citrus fruit were stored at 0° Fahrenheit for two months prior to analyses. This time period is not considered unduly long; however, no storage stability data were submitted to show fosetyl-Al was stable under these conditions. The Agency is requiring these data to be submitted.

10. Radiolabeled studies on the uptake, translocation and metabolism of fosetyl-Al in plants show that the chemical proceeds through hydrolytic cleavage of the ethyl ester, with phosphorous acid and probably ethanol as the major plant metabolites.

11. Adequate data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of fosetyl-Al are available. The major residues were fosetyl-Al, phosphorous acid, and ethanol. The tolerances are established for the parent only, that is, fosetyl-Al.

12. No poultry or livestock studies have been required because measurable residues of fosetyl-Al are expected to occur in or on the feed commodities, pineapple bran and forage, and citrus pulp and molasses.

13. Residues of fosetyl-Al in pineapples, pineapple forage and citrus are not likely to exceed the 0.1 ppm level and no residues are detected in the processed fractions of pineapple or citrus.

The Agency has determined the two year feeding study with dogs is the study of choice to establish the acceptable daily intake (ADI) because the dog was the most sensitive species for which data on fosetyl-Al are available. The NOEL in this study was 10,000 ppm (250 mg/kg body weight/day). Using a safety factor of 100, the ADI is set at 2.5 mg/kg/day. This is equivalent to a maximum permissible intake (MPI) of 150.0 mg/day for a 60 kg person. The theoretical maximum residue contribution (TMRC) for fosetyl-Al based on the established tolerances for pineapples and citrus and a daily food intake of 1.5 kg is 0.00617 mg/kg. This represents 0.004 percent of the MPI.

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions and Rationales

1. None of the risk criteria listed in 40 CFR 154.7 for initiating a Special Review have been met. Therefore, fosetyl-Al is not being placed in Special Review at this time.

Rationale: After consideration of available toxicology data, the Agency has determined that no reason exists for placement of fosetyl-Al in Special Review at this time. Fosetyl-Al has been classified as a Group C carcinogen (limited evidence of carcinogenicity in animals) and appears to pose minimal risk of causing cancer in humans. The oncogenic responses observed with fosetyl-Al were confined solely to the high dose (40,000/30,000 ppm) males at one site (urinary bladder) in one species (rat). Oncogenicity testing in mice, oncogenicity testing on the major metabolite of fosetyl-Al, and mutagenicity assays were all negative for oncogenic effects.

2. An interim 24-hour reentry interval is being imposed for all fosetyl-Al products with crop uses.

Rationale: Due to the potential for eye irritation resulting from exposure to foliar residues of fosetyl-Al, this interval is needed to protect farmworkers reentering treated areas. Unprotected persons (i.e., workers not wearing protective clothing) will be prohibited from entering sites for a 24-hr. period. Although the formulated end use product is classified as Toxicity Category III, technical fosetyl-Al is in Toxicity Category I. Reentry intervals are established based on the toxicity of the technical material because the concern is with exposure to the active ingredient. A 24-hour reentry interval is imposed for sites as an interim measure since exposure data requirements under 40 CFR Section 158.140 have not been submitted. These data are required under this Standard. Once these data are received and evaluated, the reentry interval will be reassessed.

3. The Agency is not requiring an endangered species statement on registered products containing fosetyl-Al.

Rationale: Fosetyl-Al demonstrated a very low toxicity to terrestrial animals and the residues are not expected to accumulate in the environment. Minimal exposure is anticipated for endangered aquatic species. The chemical degrades in the environment through the hydrolysis of the ethyl ester bond with subsequent degradation of the ethanol into carbon dioxide. The phosphorus acid metabolite is expected to form precipitates with aluminum, calcium, or iron in the soil. The aerobic half-life of fosetyl-Al in soil with air present is approximately 1.5 hours. The intermediate metabolites in grapes, pineapples, and the rat are ethanol and phosphorus acid.

4. It is the Agency's position that, in order to remain in compliance with FIFRA, a restriction prohibiting livestock from grazing in treated citrus groves is imposed.

Rationale: Although no detectable (<0.1 ppm) residues are expected to occur in or on pineapples, citrus, or pineapple forage, there may be higher residues on the grass in treated citrus groves; if these residues are consumed they might be detectable in livestock and the resulting food would be considered adulterated.

B. Criteria for Registration

To be registered or reregistered under this Standard, products must contain fosetyl-Al as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. Acceptable Ranges and Limits

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain fosetyl-Al as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and end-use products containing fosetyl-Al provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below. The Use Index lists all registered uses, as well as approved maximum application rates and frequencies.

- Terrestrial, food uses on:

  pineapple crowns (seed pieces) and citrus

- Terrestrial, non-food uses on:

  ornamentals (including alaonema, azalea, bougainvilla, boxwood, hibiscus, Japanese andromeda, Japanese holly, juniper, leatherleaf fern, Monterey pine, Pittosporium, pothos, rhododendron, and Schefflera), ornamental turf, and non-bearing citrus.

- Domestic, outdoor uses on:

  ornamentals (as specified above).

- Greenhouse, non-food uses on:

  ornamentals (as specified above).

D. Required Labeling

End-use or manufacturing-use pesticide products containing fosetyl-Al may not be released for shipment by a registrant or producer of that product after March 30, 1989 unless the product bears amended labeling which complies with this Registration Standard.

End-use or manufacturing-use pesticide products containing fosetyl-Al may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after March 30, 1990 unless the product bears amended labeling which complies with this Registration Standard. After review of data to be submitted under this standard, the Agency may impose additional labeling requirements.

1. **All Products**. All products are to bear appropriate labeling as specified in 40 CFR 162.10. Specific information regarding label requirements is included in Appendix II.

Fosetyl-Al is not designated as an acute or toxic hazardous waste under the Resource Conservation and Recovery Act (RCRA). The label is to bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

The labels of all products are to bear the appropriate container disposal statement (see Appendix III).

2. Manufacturing Use Products. Labels of all MPs are to bear the statement:

   "For formulation into end-use fungicide products intended only for use on citrus, pineapples, ornamentals, and turf."

   "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

   "Pesticide Handlers: During mixing, loading, or formulating of this product, wear long pants (or coveralls), long sleeved shirt, shoes, socks, goggles or face shield, and chemical/water resistant gloves."

3. End-Use Products

   a. Labels of all formulated end-use products (EP's) are to bear the statements reflecting the acute toxicity of the formulated product.

   b. All End-Use products are to bear the following statement:

      "Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters."

   c. EP products labeled for use on citrus and pineapples are to bear the following statement:

      "Do not enter into treated areas until sprays have dried. After sprays have dried, do not enter treated areas until the 24-hour reentry interval has expired. During early reentry into treated areas to perform hand labor tasks, wear long pants (or coveralls), long-sleeved shirt, shoes, socks; chemical/water-resistant gloves; goggles or face shield."

d. EP products labeled for use on citrus are to bear the following statement:

> "Note - Do not graze or feed forage from treated groves to livestock."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B[2]
3. The labeling requirements specified for manufacturing use products in Section IV.
4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

2. If eligible for the formulator's exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. **You will submit the data yourself.**

2. **You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide**

EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other

registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months of receipt of this document, you must submit to the Product Manager:

Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

Within 9 months from the receipt of this document, you must submit to the Product Manager:

Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

E. Addresses

The required information must be submitted to the following address:

Lois Rossi
Product Manager 21
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

GUIDE TO TABLES

Tables A and B contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test 1/ Substance	Use 2/ Patterns	Does EPA Have Data?4/	Bibliographic Citation4/	Must Additional Data be Submitted?	Time Frame3/ for Submission
§158.120 Product Chemistry5/						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	YES	00098326	NO	
61-3 - Discussion of Formation of Impurities	TGAI	All	YES	00098326	NO	
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	YES	00098326	NO	
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	YES	00098325	NO	
63-3 - Physical State	TGAI	All	YES	00098325	NO	
63-4 - Odor	TGAI	All	YES	00098325	NO	
63-5 - Melting Point	TGAI	All	YES	00098325	NO	
63-6 - Boiling Point	TGAI	All	N/A			

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test 1/ Substance	Use 2/ Patterns	Does EPA Have Data? 4/	Bibliographic Citation 4/	Must Additional Data be Submitted?	Time Frame for 3/
§158.120 Product Chemistry (Continued) 5/						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	YES	00098326	NO	
63-8 - Solubility	TGAI or PAI	All	YES	00098325	NO	
63-9 - Vapor Pressure	PAI	All	N/A			
63-10 - Dissociation constant	PAI	All	YES	00098325	NO	
63-11 - Octanol/water partition coefficient	PAI	All	YES	00098325	NO	
63-12 - pH	TGAI	All	YES	00098325	NO	
63-13 - Storage Stability	TGAI	All	YES	00098325	YES	15 months
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	All	YES	00098325	NO	

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

FOOTNOTES:

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; PAI = Pure active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic; Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes which begin upon receipt of the Guidance Document.

4/ Although product chemistry data may have been submitted in past, the Agency has determined that these must be resubmitted for each pesticide registration. Bibliographic citations listed in the tables would not apply to new registrations.

5/ Although product chemistry data may been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test 1/ Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for 2/ Submission
§158.125 Residue Chemistry					
171-2 - Chemical Identity	TGAI	YES	00098326	NO	
171-3 - Directions for Use	—				
171-4 - Nature of Residue (Metabolism)		YES	00139527 00148619	NO	
- Plants	PAIRA	YES	00103249 00103250 00148290	NO	
- Livestock	PAIRA & Plant Metabolites	Not applicable			
171-4 - Residue Analytical Method					
- Plant residues	TGAI & Metabolites	YES	00148619 00147569	NO	
- Animal residues	TGAI & Metabolites	Not applicable			
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop 1 Pineapples					
-- Crop field trials	TEP	YES	00139527 3/ 00148619 00103250	YES	12 months
-- Processed Food/Feed	EP	Not applicable			
-- Meat/Milk/ Poultry/Eggs	TGAI or Plant Metabolites	Not applicable			

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test[1] Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[2] Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue - Residue Studies					
o Crop 2, Citrus					
-- Crop Field Trials	TEP	YES	00148290[3]	YES	12 months
-- Processed Food/Feed	EP	Not applicable			
— Meat/Milk/ Poultry/Eggs	TGAI or Plant Metabolites	Not applicable			
- Potable Water	EP				
- Fish	EP				
- Irrigated Crops	EP				
- Food Handling	EP				
171-13 - Submittal of Analytical Reference Standards	PAIRA	YES		NO	

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

FOOTNOTES:

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted within the indicated timeframes which begin upon receipt of the Guidance Document.

3/ The Agency is requesting a study on the stability of fosetyl-Al during storage. This study was not required for the purpose of establishing tolerances; however, the Agency wishes to confirm the stability of fosetyl-Al.

LE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test1/ Substance	Use2/ Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for3/ Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	B,F,H	YES	00098370	NO	
Photodegradation						
161-2 - In water	TGAI or PAIRA	B	YES	00098371	NO	
161-3 - On soil	TGAI or PAIRA	N/A	YES	00098371	NO	
161-4 - In Air	TGAI or PAIRA	N/A	YES	00098371	NO	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	B,F	YES	00106018 00098372	NO	
162-2 - Anaerobic Soil	TGAI or PAIRA	N/A	NO4/		NO	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	N/A	YES	00147361	NO	
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A	NO5/		NO	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	B,F,H F,H	YES YES	00098375 00106019	NO NO	
163-2 - Volatility (Lab)	TEP	F	NO		NO	
163-3 - Volatility (Field)	TEP	F	NO6/		NO	

TA_ A

GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test[1]/ Substance	Use[2]/ Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3]/ Submission
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	B,H	NO[7]/		NO	
164-2 - Aquatic (Sediment)	TEP	N/A	NO[5]/		NO	
164-3 - Forestry	TEP	N/A	NO[5]/		NO	
164-4 - Combination and Tank Mixes	TEP	N/A	NO		NO	
164-5 - Soil, Long-term	TEP	N/A	NO[7]/		NO	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	N/A	NO[8]/		NO	
165-2 - Rotational Crops (Field)	TEP	N/A	NO[8]/		NO	
165-3 - Irrigated Crops	TEP	N/A	NO[5]/		NO	
165-4 - In Fish	TGAI or PAIRA	B	NO[9]/		NO	
165-5 - In Aquatic Non-Target Organisms	TEP	N/A	NO[9]/		NO	

BLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test[1]/ Substance	Use[2]/ Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3]/ Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	**TEP**	A	**NO**		YES[10]/	12 months
132-1 - Soil Dissipation	**TEP**	A	**NO**		NO	
133-3 - Dermal Exposure	**TEP**	A	**NO**		NO[11]/	
133-4 - Inhalation Exposure	**TEP**	A	**NO**		NO[11]/	
§158.142 Spray Drift						
201-1 - Droplet Size Spectrum	**TEP**		**NO**		NO	
201-1 - Drift Field Evaluation	**TEP**		**NO**		NO	

TA. . A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

FOOTNOTES:

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic; Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes which begin upon receipt of the Guidance Document.

4/ The anaerobic aquatic study satisfies the anaerobic soil requirement.

5/ Use pattern does not require this study.

6/ Active ingredient is a mineral salt--volatility studies not required.

7/ Not required because of extremely short half-life.

8/ The crop use on pineapple and citrus doesn't require crop rotation data-- pineapple and citrus not rotated crops.

9/ Not required because of low octanol/water coefficient and short 1/2-life.

10/ A 24-hour interim re-entry interval is imposed for farm workers and maintenance personnel until acceptable re-entry data are received by the Agency. The interim interval is imposed on all crops that require hand harvesting, pruning, and other high intensity worker contact with treated foliage.

11/ Not required if acceptable foliar dissipation data are submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Date Requirement	Test[1]/ Substance	Use[2]/ Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for[3]/ Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,F,H	YES	00098330	NO[4]/	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,F,H	YES	00098331	NO	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B,F,H	YES	00098332	NO	
81-7 - Delayed Neurotoxicity - Hen	TGAI	Not applicable				
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent, and	TGAI	A,B,F,H	YES	00098336	NO[5]/	
- Non-rodent (Dog)				00098337		
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,F,H	YES	00098338	NO	
82-3 - 90-Day Dermal - Rabbit	TGAI	Not applicable				
82-4 - 90-Day Inhalation: - Rat	TGAI	Not applicable				
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	Not applicable				
- Mammal	TGAI	Not applicable				

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test[1]/ Substance	Use[2]/ Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3]/ Submission
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species: - Rodent, and - Non-rodent (Dog)	TGAI	A,B,F,H	YES	00098339 00098353[5]/ 00098340	NO	
83-2 - Oncogenicity - 2 species: - Rat (preferred), and - Mouse (preferred)	TGAI	A,B,F,H	YES	00098339 00098352[6]/ 00098353	NO	
83-3 - Teratogenicity - 2 species: - Rat - Rabbit	TGAI	A,B,F,H	YES	00098347 00114091	NO	
83-4 - Reproduction - Rat 2-generation	TGAI	A,B,F,H	YES	00098348	NO	
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,F,H	YES	00098343	NO	
84-2 - Structural Chromosomal Aberration	TGAI	A,B,F,H	YES	00098345 00098343	NO	
84-4 - Other Genotoxic Effects	TGAI	A,B,F,H	YES	00098345	NO	

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test[1]/ Substance	Use[2]/ Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3]/ Submission
§158.135 Toxicology - Continued						
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B,F,H	YES	00098358	NO	
85-2 - Dermal Penetration	Choice	Not applicable				
86-1 - Domestic Animal Safety	Choice	Not applicable				

FOOTNOTES:

[1]/ Composition: TGAI = Technical Grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.

[2]/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic, Outdoor; I = Indoor.

[3]/ Data must be submitted within the indicated timeframes which begin upon receipt of the Guidance Document.

[4]/ The rabbit oral LD_{50} is used to fulfill this requirement because it is the most sensitive species for oral toxicity.

[5]/ The 90-day feeding studies requirements are superceded by the chronic feeding studies listed in 83-1.

[6]/ Study was conducted with phosphorous acid metabolite.

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-Al

Data Requirement	Test[1]/ Substance	Use[2]/ Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3]/ Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,F,H	YES	00098360	NO	
71-2 - Avian Subacute Dietary Toxicity	TGAI	A,B,F,H	YES		NO	
- Upland Game Bird, and						
- Waterfowl				00098362 00098363		
71-3 - Wild Mammal Toxicity	TGAI	A,B	NO		NO[4]/	
71-4 - Avian Reproduction	TGAI	A,B	NO		NO[5]/	
- Upland Game Bird, and						
- Waterfowl						
71-5 - Simulated Field Testing	TEP	A,B	NO		NO	
- Mammals, and						
- Birds						
- Actual Field Testing	TEP	A,B	NO		NO	
- Mammals, and						
- Birds						

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test1/ Substance	Use2/ Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for3/ Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity	TGAI	A,B,F,H	YES		NO	
- Coldwater Fish Species, and				00119526		
- Warmwater Fish Species				00128944		
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,F,H	YES	01128943	NO	
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	[A,B]6/	YES		NO	
- Fish				00147360		
- Mollusk				00147359		
- Shrimp				00098368		
72-4 - Fish Early Life Stage, and - Aquatic Invertebrate Life-Cycle	TGAI	Not applicable				
72-5 - Fish - Life-Cycle	TGAI	Not applicable				

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test[1/] Substance	Use[2/] Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3/] Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	Not applicable				
- Crustacean						
- Fish						
- Insect Nymph						
- Mollusk						
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	Not applicable				
- Actual Field Testing -Aquatic Organisms						

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

FOOTNOTES:

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic; Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes which begin upon receipt of the Guidance Document.

4/ There is no requirement since the mammalian toxicity data indicate that the chemical will pose a low potential risk to wild animals.

5/ These data are not required for the uses covered by the standard based on the short half-life of fosetyl-Al under aerobic conditions and the octanol/water partition coefficient that indicate persistence and accumulation is not expected. These data may be required for additional uses.

6/ Required to support the citrus and turf uses.

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test[1]/ Substance	Use[2]/ Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3]/ Submission
§158.150 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	EP	B	NO		NO	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	B	NO		NO	
122-1 - Vegetative Vigor	TGAI	B	NO		NO	
122-2 - Aquatic Plant Growth	TGAI	B	NO		YES[4]/	9 months
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	B	NO		NO	
123-1 - Vegetative Vigor	TGAI	B	NO		NO	
123-2 - Aquatic Plant Growth	TGAI	B	NO		Reserved[5]/	
TIER III						
124-1 - Terrestrial Field	TEP	B	NO		NO	
124-2 - Aquatic Field	TEP	B	NO		Reserved[6]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

FOOTNOTES:

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic; Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes which begin upon receipt of the Guidance Document.

4/ Required due to the persistence in water (hydrolysis degradation less than 10% after one month).

5/ Reserved based on the results of Section 122.2-Aquatic Plant Growth (Tier I).

6/ Reserved based on the results of section 123.2-Aquatic Plant Growth (Tier II).

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

Data Requirement	Test[1]/ Substance	Use[2]/ Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3]/ Submission
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A,B,H	NO		YES	9 Months
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,H	NO		Reserved[4]/	
141-4 - Honey bee subacute feeding study	(Reserved)					
141-5 - Field testing for pollinators	TEP	A,B,H	NO		Reserved[4]/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	(Reserved)					
142-1 - Aquatic insect life-cycle study	(Reserved)					
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)					

TABLE A
GENERIC DATA REQUIREMENTS FOR FOSETYL-AL

FOOTNOTES:

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food: G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes which begin upon receipt of the Guidance Document.

4/ Requirement is reserved pending receipt of data from the acute contact study (141-1).

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FOSETYL-AL

Data Requirement	Test[1] Substance	Use[2] Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3] Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	YES	00098325	NO	
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	YES	00098325	NO	
61-3 - Discussion of Formation of Impurities	MP	All	YES	00098325	NO	
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	YES	00098325	NO	
62-2 - Certification of Limits	MP	All	YES	00098325	NO	
62-3 - Analytical Methods to Verify Certified Limit	MP	All	YES	00098327	NO	
Physical and Chemical Characteristics						
63-2 - Color	MP	All	YES	00098325	NO	
63-3 - Physical State	MP	All	YES	00098325	NO	
63-4 - Odor	MP	All	YES	00098325	NO	

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FOSETYL-AL

Data Requirement	Test[1] Substance	Use[2] Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3] Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	YES	00098325	NO	
63-12 - pH	MP	All	YES	00098325	NO	
63-14 - Oxidizing or Reducing Action	MP	All	YES	00098325	NO	
63-15 - Flammability	MP	All	YES	00098328	NO	
63-16 - Explodability	MP	All	YES	00098328	NO	
63-17 - Storage Stability	MP	All	YES	00098325	YES	6 months
63-18 - Viscosity	MP	All	Not applicable			
63-19 - Miscibility	MP	All	Not applicable			
63-20 - Corrosion Characteristics	MP	All	YES	00098325	NO	
Other Requirements:						
64- 1 - Submittal of samples	MP	All	YES	00098325	NO	

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FOSETYL-AL

FOOTNOTES:

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. MP = Manufacturing-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food: G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes which begin upon receipt of the Guidance Document.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FOSETYL-AL

Data Requirement	Test 1/ Substance	Use 2/ Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for 3/ Submission
§158.135 Toxicology ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	A,B,F,H	YES	00098330	NO	
81-2 - Acute Dermal Toxicity - Rabbit	MP	A,B,F,H	YES	00098331	NO	
81-3 - Acute Inhalation Toxicity - Rat	MP	A,B,F,H	YES	00098332	NO	
81-4 - Primary Eye Irritation - Rabbit	MP	A,B,F,H	YES	00098333	NO	
81-5 - Primary Dermal Irritation - Rabbit	MP	A,B,F,H	YES	00098334	NO	
81-6 - Dermal Sensitization - Guinea Pig	MP	A,B,F,H	YES	00098335	NO	

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. MP = Manufacturing-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food: G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes which begin upon receipt of the Guidance Document.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING FOSETYL-AL

Data Requirement	Test[1] Substance	Use[2] Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3] Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	EP	All	Partially	Reg.Jacket (359-706)	YES[4]	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	EP	All	NO		YES[5]	6 months
61-3 - Discussion of Formation of Impurities	EP	All	NO		YES[6]	6 months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	EP	All			NO[7]	
62-2 - Certification of Limits	EP	All	NO		YES[8]	12 months
62-3 - Analytical Methods to Verify Certified Limit	EP	All			YES[9]	12 months
Physical and Chemical Characteristics						
63-2 - Color	EP	All	YES	00098325	NO	
63-3 - Physical State	EP	All	YES	00098325	NO	
63-4 - Odor	EP	All	YES	00098325	NO	

TABLE C

PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING FOSETYL-AL

Data Requirement	Test[1/] Substance	Use[2/] Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3/] Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	EP	All	YES	00098325	NO	
63-12 - pH	EP	All	Partially	00098325	YES[10/] [11/]	6 months
63-14 - Oxidizing or Reducing Action	EP	All	NO	00098325	NO[10/] [12/]	
63-15 - Flammability	EP	All	NO		YES[10/] [13/]	6 months
63-16 - Explodability	EP	All	NO		YES[10/] [14/]	6 months
63-17 - Storage Stability	EP	All	NO		YES[10/]	15 months
63-18 - Viscosity	EP	All	NO		YES[10/] [15/]	6 months
63-19 - Miscibility	EP	All	NO		YES[10/] [16/]	6 months
63-20 - Corrosion Characteristics	EP	All	NO		YES[10/]	15 months
63-21 - Dielectric Breakdown Voltage	EP	All	NO		YES[10/] [17/]	6 months
Other Requirements:						
64- 1 - Submittal of samples	EP	All	Not Applicable		NO	

T/ C

PRODUCT SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCTS CONTAINING FOSETYL-AL

FOOTNOTES:

1/ EP = End-Use Product

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food: G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes which begin upon receipt of the Guidance Document.

4/ The chemical name, nominal concentration, Chemical Abstracts Service (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert ingredient must be provided. For the active ingredient, the following must also be provided: the product name, trade name, and common name; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

5/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, a statement of whether the process for producing the product involves intended chemical reactions, equipment used to produce the final product, purification procedures, and quality control measures. In addition, the name and address of the manufacturer producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

6/ A detailed discussion of all impurities that are or may be present at >0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side), if any, in the manufacturing process, and any contamination during and after production must be submitted.

7/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used. A preliminary analysis of end-use products must produced by an integrated formulation system are required on a case-by-case basis only.

8/ Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at >0.1% (w/w) and each "toxicologically significant" impurity present at <0.1% (w/w) must be provided and certified. A statement regarding the accuracy and precision of the stated limits should also be provided. Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570-4 (Rev. 2-85).

9/ Analytical methods must be provided to determine the active ingredient, toxicologically significant impurity, or intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

10/ Physicochemical characteristics (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, corrosion characteristics, and dielectric breakdown voltage) as required in 40 CFR Part 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING FOSETYL-AL

FOOTNOTES:

11/ Required if the test substance is dispersible with water.
12/ Required if the product contains an oxidizing or reducing agent.
13/ Required if the product contains combustible liquids.
14/ Required if the product is potentially explosive.
15/ Required if the product is a liquid.
16/ Required if the product is a liquid and is to be diluted with petroleum solvents.
17/ Required if the product is a non-conductant liquid and is intended for use in or around electrical equipment.

TAB.

PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING FOSETYL-AL

Data Requirement	Test[1/] Substance	Use[2/] Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for[3/] Submission
§158.135 Toxicology ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	EP	All	YES	00122781	NO	
81-2 - Acute Dermal Toxicity - Rabbit	EP	All	YES	00122782	NO	
81-3 - Acute Inhalation Toxicity - Rat	EP	All	YES	00122783	NO	
81-4 - Primary Eye Irritation - Rabbit	EP	All	YES	40131101	NO	
81-5 - Primary Dermal Irritation - Rabbit	EP	All	YES	00122785	NO	
81-6 - Dermal Sensitization - Guinea Pig	EP	All	NO	-	YES	6 months

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1/ Composition: EP = End-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food: G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframes which begin upon receipt of the Gudance Document.

APPENDIX II

LABELING

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead o the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED U PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. unit

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC$_{50}$	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter	Greater than 20 mg/liter.
Dermal LD$_{50}$	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

APPENDIX III

USE INDEX

123301

ALUMINUM TRIS (O-ETHYL PHOSPHONATE)*

TYPE PESTICIDE: Fungicide

FORMULATIONS:
Tech (95%)
WP (80%)

GENERAL WARNINGS AND LIMITATIONS: Workers should wear full protective clothing (long pants, long sleeve shirt and water resistant gloves) when applying this product or during the mixing and loading operations. Do not apply this product in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons. Do not enter treated areas without protective clothing until spray is dried.
Do not mix with any sticker, extender or wetting agent.
Dosage rates are given in active ingredient.

Definition of Terms:
N.F. - Non-food use.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP		
	(Agricultural Crops)		
/02000AA /02000DA	Citrus (Non-bearing) (for trees that will not produce marketable fruit for 12 months after the last application)		N. F. May be used in all areas except California. Do not exceed 4 applications per year and 100 gallons per acre per application. Do not allow livestock to graze in treated citrus groves.
FICEPCN FICBPCN	Phytophthora foot rot Phytophthora root rot	4.0 lb/ 100 gal (80% WP)	Foliar treatment. Apply as a spray to run-off at each leaf flush. Nursery trees, resets, and new plantings should be treated at time of planting.

*fosetyl-Al
*Aliette®

	Site and Pest	Dosages and Formulation(s)	Tolerances, Use, Limitations
	Citrus (continued)		
/02000AA	Citrus		0.1 ppm. Do not apply within 90 days of harvest. Do not exceed 4 applications per year and 1500 gallons per acre per application. Do not allow livestock to graze in treated citrus groves.
FICEPCN FICBPCN	Phytophthora foot rot Phytophthora root rot	4.0 lb/ 100 gal (80% WP)	Foliar treatment. Apply as a spray to run-off at each leaf flush (i.e., March, May, July and September).
/06013AA /06013DA	Pineapple		0.1 ppm for pineapple 0.1 ppm for pineapple fodder 0.1 ppm for pineapple forage Do not apply within 9 months of harvest.
IBIPJN	Heart rot (Phytophthora parasitica)	2.0 lb/ 100 gal/A[1] (80% WP)	Dip treatment. Apply as a pre-plant dip to pineapple slips (seed-pieces) immediately prior to planting.
		1.0 lb/ 100 gal (80% WP)	Foliar treatment. Use up to 300 gallons per acre. A maximum of 4 sprays per year may be applied at 3 month intervals. Apply to established plants, when aggravating environmental conditions (i.e. excessive rainfall) occur or are anticipated.

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[1] 100 gallons is intended to treat the number of slips required to plant one acre.

ALUMINUM TRIS (O-ETHYL PHOSPHONATE)

	Site and Pest	Dosages and Formulation(s)	Tolerances, Use, Limitations
	TERRESTRIAL NON-FOOD CROP		
	(Lawns and turf (including ground cover))		
/33007AA /33008AA	Golf Course Turf (golf fairways, greens and tees) Ornamental Turf (sod farm)		Do not graze animals on treated turf. Do not feed clippings from treated turf to livestock or poultry. Do not mow and/or water areas until foliage is completely dry. Maintain agitation during spray operation.
FBAAPES	Pythium blight	3.2-6.4 oz/ 1,000 sq ft (80% WP)	Foliar application. Apply as a foliar spray , using 1 to 5 gallons of water per 1000 square feet. The lower rate is applied using a 14 day interval between applications and the higher rate using a 21 day interval. Begin preventive application when conditions first favor disease development.
	(Ornamental Plants and Forest Trees)		
/34022AA /34022DA	Azalea (Rhododendron spp.)		
/34031AA /34031DA	Boxwood (Buxus sempervirens)		
/34078AA /34078DA	Japanese Andromeda (Pieris japonica)		
/34080AA /34080DA	Japanese Holly (Ilex crenata)		
/35073AA /35073DA	Juniper (Juniperus spp.)		
/35196AA /35196DA	Monterey Pine (Pinus radiata)		
/34113AA /34113DA	Pittosporum (Pittosporum spp.)		
/31175AA /31175DA	Schefflera (Schefflera spp.)		
/34118AA /34118DA	Rhododendron (Rhododendron spp.)		

ALUMINUM TRIS (O-ETHYLTPHOSPHONATE)

	Site and Pest	Dosages and Formulation(s)	Tolerances, Use, Limitations
	(Ornamental Plants and Forest Trees) (continued)		
FICBPCN	Phytophthora root rot (Phytophthora sp.)	5.2-10.4 oz/ yd^3 (80% WP)	Soil incorporation. Incorporate into the potting mixture as it is being prepared. Under severe disease conditions the higher rate should be used.
		0.8-1.6 lb/ 1000 sq ft (80% WP)	Drench application. Apply in 62.5 to 187.5 gallons per 1000 square feet (0.5 to 1.5 pints per square foot). May be used in conjunction with soil incorporation. Begin application at potting or prior to anticipated disease development. Continue application (monthly) as long as conditions are favorable for disease development. Under severe disease conditions the higher rate should be used.
/31014AA	Aglaonema (Aglaonema spp.)		May be used in all areas except California.
/34022AA	Azalea (Rhododendron spp.)		
/34030AA	Bougainvillea (Bougainvillea spp.)		
/34031AA	Boxwood (Buxus sempervirens)		
/34069AA	Hibiscus (Hibiscus spp.)		
/35073AA	Juniper (Juniperus spp.)		
/39010AA	Leatherleaf fern (Rumohra adaintiformis)		
/34113AA	Pittosporum (Pittosporum spp.)		
/34116AA	Pothos (Pothos spp.)		
/34118AA	Rhododendron (Rhododendron spp.)		
FKAZPCN	Phytophthora (disease complex)	2.0-4.0 lb/ 100 gal (80% WP)	Foliar application. Begin application at potting or prior to anticipated disease development. Spray foliage and plant parts until wet. Continue at monthly intervals as long as conditions are favorable for disease development. Under severe disease conditions, the higher rate should be used.
FKAZPES	Pythium (disease complex)		

	Site and Pest	Dosages and Formulation(s)	Tolerances, Use, Limitations
	(Ornamental Plants and Forest Trees) (continued)		
	GREENHOUSE NON-FOOD CROP		
/31014CA	Aglaonema (Aglaonema spp.)		
/34022CA	Azalea (Rhododendron spp.)		
/34030CA	Bougainvillea (Bougainvillea spp.)		
/34031CA	Boxwood (Buxus sempervirens)		
/34069CA	Hibiscus (Hibiscus spp.)		
/34078CA	Japanese Andromeda (Pieris japonica)		
/34080CA	Japanese Holly (Ilex crenata)		
/35073CA	Juniper (Juniperus spp.)		
/39010CA	Leatherleaf fern (Rumohra adaintiformis)		
/35196CA	Monterey Pine (Pinus radiata)		
/34113CA	Pittosporum (Pittosporum spp.)		
/34116CA	Pothos (Pothos spp.)		
/34118CA	Rhododendron (Rhododendron spp.)		
/31175CA	Schefflera (Schefflera spp.)		

Refer to:
TERRESTRIAL NON-FOOD CROP (Ornamental Plants and Forest Trees), for ornamental plant and forest tree pest, use and limitation information.

ALUMINUM TRIS (O-ETHYL PHOSPHONATE)

Listing of Registered Pesticide Products by Formulation

&095.0001 95% technical chemical
  aluminum tris (o-ethyl phosphonate) (123301)
    000359-00705

&080.0006 80% wettable powder
  aluminum tris (o-ethyl phosphonate) (123301)
    000359-00706

EPA Index to Pesticide Chemicals

ALUMINUM TRIS (O-ETHYL PHOSPHONATE)

Auxiliary Documentation

SLN [24 (c)] registration # FL85000300 is currently on the books as a valid "special local need" registration for the state of Florida. A review of this registration jacket indicates that its use pattern has been superceded by the May 13, 1985 update of the parent product, #000359-00706, a regular section 3 registration. Consequently there was no need to address this SLN registration in this index entry.

Signed:

J. Dean Hansen
Plant Pathologist
08 April 1986

APPENDIX IV

BIBLIOGRAPHY

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

APPENDIX IV

Registration Standards Case 0646: Fosetyl-Al

BIBLIOGRAPHY OF STUDIES CONSIDERED IN SUPPORT OF REGISTRATION UNDER THE STANDARD

All studies in this bibliography are usable only with the permission of their submitter--Rhone-Poulenc--under the provisions of FIFRA §3(c)(1)(D)(i), for the ten-year period beginning with the date of first product registration under this standard.

MRID	CITATION
00098325	Rhone-Poulenc Chemical Company (1981) Product Chemistry: [Fosetyl-Al]. Includes method LS 74.783 dated Jul 7, 1980, method dated May 7, 1981 and undated method RE-18-81. (Compilation; unpublished study received Apr 5, 1982 under 359-705; CDL:247159-A)
00098326	Bertrand, A. (1981) Fosetyl-Al: Composition of the Technical Grade Industrial Product (Analysis of 5 Typical Batches): Ref: AG/CRLD/An AB/SV 164. Includes method P-286-06-80 and method P.306.03.81. (Unpublished study received Apr 5, 1982 under 359-705: prepared by Rhone-Poulenc Agrochimie, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247159-B)
00098327	Rhone-Poulenc Agrochimie (1980) Fosetyl-Al or Ca (O-ethyl Phosphonate Salts of Aluminium or Calcium) Lodometric Determination in the Technical compounds and formulations. Method P-286-06-80 Dated Jul 17, 1980. (Translation; unpublished study received Apr 5, 1982 under 359-705; Submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247159-C)
00098328	Rhone-Poulenc Agrochimie (19??) Fosetyl-Al Technical Stability to Heat, Inflammability Explosivity: AG/RD/DARGOIRE SRPH JD/NC/177. (Unpublished study received Apr 5, 1982 under 359-705; submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247159-D)
00098330	Pasquet, J.; Mazuret, A.; Maratrat, ?; et al. (1977) LS 74-783 (Aluminium Ethyl Phosphite; 32 545 R.P., Aluminium Salt): Acute toxicity in the Rat and Rabbit: R.P./R.D./C.N.G. No. 19 143-E. (Translation; unpublished study received Apr 5, 1982 under 359-705; prepared by Rhone-Poulenc, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247160-B)
00098331	Pasquet, J.; Mazuret, A.; Kalifat, R.; et al. (1981) Fosetyl-Al (32 545 R.P., Aluminium Salt): Acute Percutaneous Toxicity in the Rabbit: Reference C.R. Vitry/C.N.G. No. 21 162-E. (Translation; unpublished study received Apr 5, 1982 under 359-705; prepared by Rhone-Poulenc Industries, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247160-C)

MRID	CITATION
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00098333	Pasquet, J.; Mazuret, A.; Maratrat, ?; et al. (1981) Fosetyl-Al (32 545 R.P., Aluminium salt): Primary Eye Irritation in the Rabbit: Reference C.R. Vitry/C.N.G. No. 21 163-E. (Translation; unpublished study received Apr 5, 1982 under 359-705; prepared by Rhone-Poulenc Industries, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247160-E)
00098334	Pasquet, J.; Mazuret, A.; Maratrat, ?; et al (1981) Fosetyl-Al (32 545 R.P., Aluminium Salt): Primary Skin Irritation in the Rabbit: reference C.R. Vitry/C.N.G. No. 21 164-E. (Translation; unpublished study received Apr 5, 1982 under 359-705; prepared by Rhone-Poulenc Industries, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247160-F)
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00098337	Coquet, B.; Clair, M. (1977) LS 74783 (Aluminium Ethylphosphite): 3 Month Oral Toxicity Study in the Dog: IFREB-R 712110. A translation of: LS 74783 (Ethylphosphite D'Aluminium): Toxicite a Terme (3 mois) Par Voie orale Chez le Chien: IFREB-R 709235. (Unpublished study received Apr 5, 1982 under 359-705; prepared by Institut Francais de Recherches et Essais Biologiques, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247161-B)
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00098343	Bouanchaud, D.H.; Cartier, J.R.; Vessieres, ? (1981) Fosetyl-al (32 545 R.P., Aluminum Salt): Supplementary Studies of Mutagenesis in Microorganisms: C.R. Vitry/C.N.G. No. 21 212. (Unpublished study received Apr 5, 1982 under 359-705; prepared by Rhone-Poulenc Industries, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL: 247173-B)
00098345	Cordier, A.; Fournier, E.; Viziere, ? (1981) Fosetyl-al (32 Sys R.P., aluminium Salt): Micronucleus Test in the Mouse by the Oral Route: Reference C.R. Vitry/C.N.G. No. 21 186-E. (Translation, unpublished study received Apr 5, 1982 under 359-705; prepared by Rhone-Poulenc Industries, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL: 247173-D)
00098347	Pasquet, J.; Le Bail, R.,; Cegeral, ? (1976) Compound LS 74-783; Oral Teratogenicity Study in the Rabbit: Report R.P./R.D./C.N.G. No. 18917-F. (Translation; unpublished study received Apr 5, 1982 under 359-705; prepared by Rhone-Poulenc, France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247174-A)
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00098360	Roberts, N.L.; Phillips, C.N.K. (1981) The Acute Oral Toxicity (LD_{50}) of LS 74.783 to the Bobwhite Quail: RNP 189 WL/81148. Final report. (Unpublished study received Apr 5, 1982 under 359-705; prepared by Huntingdon Research Centre, England, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247184-B)
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00098370	Buys, M.; Bertrand,; Giraud, J.P. (1981) Fosetyl-al (Aluminium Tris-O-ethylphosphonate) Hydrolysis Study: Ref. AG/CRLD/An/AB/MB/JPG/CB/613.81. (Unpublished study received Apr 5, 1982 under 359-705; prepared by Rhone-Poulenc Agrochemie S.A., France, submitted by Rhone-Poulenc Chemical Co., Monmouth Junction, N.J.; CDL:247185-B)

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00103250	Laurent, M.; Chabassol, Y. (1982) Fosetyl-Al (32 545 R.P., Aluminium Salt): Pineapple Metabolism Study: Report C.R. Vitry/CNG-An No. 4412-E. (Translation; unpublished study received Jun 8, 1982 under 359-706; submitted by Rhone-Poulenc, Inc., Monmouth Junction, N.J.; CDL:247647-C)
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MRID	CITATION
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APPENDIX V

FORMS

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 7580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date ____________________

Guidance Document for ________________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ____________

Registrant's Name and Address: ______________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated ________ concerning a requirement for submission of "generic" data on the active ingredient ____________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ____________________ and their registration number(s) is/are ____________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________
(Signature)

Dated: ________________

____
(Typed)

EPA Form 8570-27